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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/980,370	05/17/2002	Charles Andrew Collyer	229752001500	1330

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Morrison & Foerster
2000 Pennsylvania Avenue NW
Washington, DC 20006-1888

EXAMINER

MONDESI, ROBERT B

ART UNIT	PAPER NUMBER
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1653

DATE MAILED: 11/07/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/980,370	Applicant(s) COLLYER ET AL.	
	Examiner Robert B Mondesi	Art Unit 1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 04 November 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 12-17 and 20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 1-11, 18 and 19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s) _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

This Office Action is in response to amendment filed August 14, 2003. The applicant has withdrawn claims 12-17 and 20 from further consideration. Claim 11 has been amended. Claims 1-11 and 18-19 are currently under examination.

Amendment filed August 14, 2003 in response to notice to comply regarding paper copy of "Sequence Listings" has been entered and accepted.

Maintenance of Rejections and Objections

Specification

The use of the trademark "PERKIN ELMER" (p. 37, line 17) and "TITERTEK TWINREADER" (p.39, line 22) has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

The disclosure is objected to because it contains an embedded hyperlink (p.46, line 15) and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 3-6, 9, 18 and 19 rejected under 35 U.S.C. 103(a) as being unpatentable over Potempa et al. in view of Nakayama et al. (cited in IDS, paper #6) and Bramanti et al. Potempa et al. teach a method of using a gingipain (present claim 6, 15, 16, 19), which contains HA2 domain which comprises an amino acid sequence corresponding to a nucleotide sequence with 99.25% identity to SEQ ID NO: 5 (see p.68-73 and copy of attached sequence alignment) (present claim 9), in the manufacture of a medicament for the prevention or treatment of *P. gingivalis* infection in the oral cavity in humans (p. 3, lines 1-5 and

20-25) (present claim 3-5, 15, 18). Potempa et al. do not describe an agent, which antagonizes the interaction between a molecule-derived from *P. gingivalis* and an HA2-binding motif on a porphyrin containing molecule.

Nakayama et al. teach that *P. gingivalis* contributes to adult periodontitis and that *P. gingivalis* binds to heme and requires heme or hemoglobin for its growth. (p. 51, col.2, 3rd para. to p. 52, col. 1 .) (present claims 6, 7, 10, 19). Nakayama et al. do not teach an agent which antagonizes the interaction between a molecule derived from *P. gingivalis* and an HA2-binding motif on a porphyrin containing molecule.

Bramanti et al. teach agents, namely, protoporphyrin IX and zinc protoporphyrin (table 2) that antagonize the interaction between *P. gingivalis* and hemin, the crystalline chloride of heme (present claims 7, 8, 12, 13). Bramanti et al. do not teach a method of administering these agents to treat infection caused by *P. gingivalis*. Given the social desirability treating diseases caused by *P. gingivalis* as taught by Potempa et al., the dependency of *P. gingivalis* on interacting with a porphyrin containing molecule as taught by Nakayama et al., and the ability of protoporphyrin IX and zinc protoporphyrin to antagonize the interaction between *P. gingivalis* and hemin, it would have been obvious to one of ordinary skill in the art at the time of the invention to use the agents taught by Bramanti et al. or to use an agent to antagonize a molecule derived from *P. gingivalis* containing and HA2 domain in and an HA2-binding motif on a porphyrin containing molecule, such as heme or hemin to treat disease caused

by *P. gingivalis*. Thus, the claimed invention was prima facie obvious to make and use at the time the claimed invention was made.

Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Progulske-Fox et al. (WO 96/17936) in view of Nakayama et al. (cited in IDS, paper # 6) and Bramanti et al. Progulske-Fox et al. teach a method of using an *hagA* gene (SEQ ID NO: 1) and an HA2-containing molecule comprising an amino acid sequence with 100% identity to SEQ ID NO: 1 (see claim 4 and copy of attached sequence alignment), in the manufacture of a medicament for the prevention or treatment of *P. gingivalis* infection in the oral cavity in humans (see claim 1). Progulske-Fox et al. do not describe an agent, which antagonizes the interaction between a molecule-derived from *P. gingivalis* and an HA2-binding motif on a porphyrin containing molecule specifically.

Given the social desirability of treating diseases caused by *P. gingivalis* as taught by Progulske-Fox et al. the dependency of *P. gingivalis* on interacting with a porphyrin containing molecule as taught by Nakayama et al., and the ability of protoporphyrin IX and zinc protoporphyrin to antagonize the interaction between *P. gingivalis* and heme, it would have been obvious to one of ordinary skill in the art at the time of the invention to use the agents taught by Bramanti et al. or to use an agent to antagonize a molecule derived from *P. gingivalis* containing an HA2 domain and an HA2-binding motif, whether heme, heme, hemoglobin and salts thereof on a porphyrin containing molecule, such as heme or heme to treat disease caused by *P. gingivalis*. Thus, the claimed invention was prima facie obvious to make and use at the time the claimed invention was made.

Conclusion

No claims are allowed.

Response to Comments

Applicant did not make any comments in the response pages.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert B Mondesi whose telephone number is 703-305-4445. The examiner can normally be reached on 9am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 703-308-2923. The

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fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0198.



Robert B Mondesi
Patent Examiner
Group 1653

11-04-03



CHRISTOPHER S. F. LOW
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1000